

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

H. LUNDBECK A/S, TAKEDA)	
PHARMACEUTICAL COMPANY LTD.,)	
TAKEDA PHARMACEUTICALS U.S.A.,)	
INC., TAKEDA PHARMACEUTICALS)	
INTERNATIONAL AG and TAKEDA)	
PHARMACEUTICALS AMERICA, INC.,)	
)	
Plaintiffs,)	C.A. No. 18-88 (LPS)
)	CONSOLIDATED
v.)	
)	REDACTED - PUBLIC VERSION
ALKEM LABORATORIES LTD., et al.,)	
)	
Defendants.)	

**LETTER TO THE HONORABLE JENNIFER L. HALL FROM
JACK B. BLUMENFELD REGARDING DISCOVERY DISPUTE WITH SANDOZ**

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mdellinger@mnat.com

Attorneys for Plaintiffs

Originally Filed: September 15, 2020
Redacted Version Filed: September 22, 2020

Dear Judge Hall:

Pursuant to Fed. R. Civ. P. 26(c) and D.Del. LR 30.2, Plaintiffs respectfully request a Protective Order preventing Defendant Sandoz from taking the depositions of Dr. Fabia Gozzo and Dr. Allan Myerson [REDACTED]

[REDACTED] Good cause exists for granting the requested Protective Order because [REDACTED]

[REDACTED]—the only claims on which Drs. Gozzo and Myerson have opined. As these claims are no longer properly in the case and neither Dr. Gozzo nor Dr. Myerson will testify about them at trial, there is no basis for Sandoz to take the deposition of either expert.

I. Background

This is a Hatch-Waxman case arising from the submission of ANDAs by a number of generic drug manufacturers, including Sandoz's submission of ANDA No. 210993, seeking FDA approval to market a generic version of Plaintiffs' Trintellix[®] product. Plaintiffs sued Sandoz for infringement of certain claims of U.S. Patent Nos. 8,722,684; 8,969,355; 9,227,946; and 9,861,630 (collectively, "the Crystalline Form Patents"), as well as certain claims of the '096 Patent and U.S. Patent No. 9,125,910 ("the '910 Patent"). D.I. 1, 246, 260, 275, 801, 809. Sandoz later converted its Paragraph IV certifications for the Crystalline Form Patents to Paragraph III certifications and moved to dismiss Plaintiffs' claims for infringement of these patents. D.I. 415–16.

On April 16, Plaintiffs served expert reports from Drs. Gozzo and Myerson relating to Sandoz's infringement of the Crystalline Form Patents and claims 4 and 5 of the '096 Patent.¹ D.I. 734 at 8. No other claims of the '096 Patent were addressed in these reports nor were any other patents addressed. The Court granted Sandoz's motion to dismiss on June 26, and all claims and counterclaims relating to the Crystalline Form Patents were dismissed. D.I. 813, 814. Sandoz recently moved for dismissal of the claims and counterclaims relating to the '910 Patent without prejudice [REDACTED] Plaintiffs have not opposed that motion. D.I. 908–10, 937. Thus, only the '096 Patent remains in the case against Sandoz. D.I. 809, 883.

Shortly after the Court's dismissal of the Crystalline Form Patents, Plaintiffs informed Sandoz and the Court that they were no longer asserting claims 4 and 5 of the '096 Patent against Sandoz. D.I. 863, 883 at ¶¶ 121, 129; Ex. A. Despite telling the Court it believed the claims of the '096 Patent were not properly in the case and should be dismissed (D.I. 839 at 3; *see also* Ex. B), Sandoz told Plaintiffs that it would [REDACTED]

¹ Drs. Gozzo and Myerson submitted additional infringement reports related to other Defendants' infringement. Dr. Gozzo submitted reports for [REDACTED] Dr. Myerson submitted reports for [REDACTED]. Each such report includes information designated as Competitively Sensitive Confidential Information by those respective Defendants. Pursuant to the Protective Order in this case, Drs. Gozzo and Myerson's reports for one Defendant cannot be shared with other Defendants. Nor can one Defendant attend the infringement deposition(s) of another Defendant. D.I. 132 at ¶¶ 14–15.

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[REDACTED] Ex. C. Given Sandoz's insistence that claims 4 and 5 of the '096 Patent remained in the case, Plaintiffs served reply expert reports from Drs. Gozzo and Myerson relating exclusively to Sandoz's infringement of claims 4 and 5 of the '096 Patent.

On August 26, 2020, Plaintiffs [REDACTED] Ex. D. [REDACTED] Dr. Gozzo had been scheduled to have her depositions taken by Defendants [REDACTED] and Sandoz on September 3 and 4.² Depositions of Dr. Myerson were scheduled for August 24–28 but had to be [REDACTED]³ [REDACTED] Plaintiffs requested confirmation that Sandoz would drop its request to depose Drs. Gozzo and Myerson, as the issues on which they opined are no longer in the case. Sandoz refused to do so, contending that [REDACTED] Ex. E (quoting Ex. D.1 at 1). As explained below, there is no merit to Sandoz's position. Because Sandoz continues to demand depositions of Drs. Gozzo and Myerson, Plaintiffs initiated the instant request for relief.

II. No Case or Controversy Remains as to Claims 4 and 5 of the '096 Patent

Plaintiffs withdrew their allegations that Sandoz infringes claims 4 and 5 of the '096 Patent. D.I. 863, 883 at ¶¶ 121, 129; Ex. A. This fact alone has eliminated any case or controversy. *See Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1284 (Fed. Cir. 2012). Because Sandoz maintains its counterclaims to claims 4 and 5, Sandoz must show that a case or controversy regarding these unasserted claims continues to exist. *Id.* at 1283. It cannot do so. *Id.* at 1283–84.

[REDACTED] removes subject matter jurisdiction. *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1344, 1345–46 (Fed. Cir. 2007). Indeed, Sandoz has not shown [REDACTED] *See Medeva Pharma Suisse A.G. v. Par Pharm., Inc.*, 774 F. Supp. 2d 691, 698–99 (D.N.J. 2011) (Court did not perceive [REDACTED] as insufficient or “too limited in breadth or scope”); [REDACTED]

[REDACTED] No. 09-651-LPS, 2011 WL 13371929, at *6 n.3 (D. Del. Jul. 18, 2011).

[REDACTED] Ex. F.

² Dr. Gozzo's [REDACTED] depositions proceeded as scheduled.

³ The parties are working to reschedule Dr. Myerson's depositions.

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III. There Is No Reason for Sandoz to Depose Dr. Myerson and Dr. Gozzo

The court may, “for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense.” Fed. R. Civ. P. 26(c)(1). Good cause may be established by “showing that disclosure will work a clearly defined and serious injury to the party seeking closure.” *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (citation omitted). “[E]ven if the information sought is relevant, discovery is not allowed where no need is shown, or where compliance is unduly burdensome, or where the potential harm caused by production outweighs the benefit.” *Mannington Mills, Inc. v. Armstrong World Indus., Inc.*, 206 F.R.D. 525, 529 (D. Del. 2002).

Sandoz should not be permitted to take the depositions of Drs. Gozzo and Myerson because their testimony is no longer relevant to the claims and defenses remaining in the case. The opinions Drs. Gozzo and Myerson have offered relate only to claims 4 and 5 of the '096 Patent. [REDACTED] and Drs. Gozzo and Myerson will not be called to testify at trial. Thus, there is no reason for Sandoz to demand their depositions. *Id.* at 532 (“Where proof of either relevance *or* need is not established, discovery is properly denied.”) (citation omitted) (emphasis in original).

Such depositions would only burden Plaintiffs and their experts. Dr. Myerson is already scheduled to be deposed by the other Defendants in this case for a total of 40 hours. D.I. 829, 876. Dr. Gozzo lives and works in Switzerland where she runs a busy laboratory. Neither should be burdened with preparing for and testifying on issues that are no longer in the case. Nor should Plaintiffs be required to expend additional resources on issues that are no longer in dispute.

IV. Sandoz Improperly Seeks to Prevent Counsel from Communicating with Dr. Gozzo

Sandoz—invoking D.Del. LR 30.6—included a request in the discovery dispute letter seeking to bar Plaintiffs from communicating with Dr. Gozzo in preparation for Sandoz’s deposition of her. Sandoz’s request was added to the dispute letter just prior to its filing even though the request was never the subject of a meet and confer. Ex. G. Moreover, Sandoz has declined to submit an opening letter brief in support of this request. Ex. H. The requested relief should be denied for these reasons alone. It should also be rejected on the merits. D.Del. LR 30.6 is inapplicable. Sandoz’s deposition of Dr. Gozzo has not begun. The completed [REDACTED] depositions of Dr. Gozzo were not Sandoz’s deposition. Indeed, Defendants requested and the Court ordered that Drs. Gozzo and Myerson be separately deposed by each Defendant “on infringement issues specific and unique to that defendant.” D.I. 829, 876; D.I. 820 at 3, 858 at 1. And the Protective Order that Defendants requested and obtained prohibited Sandoz from attending Dr. Gozzo’s other depositions. D.I. 132 at ¶¶ 14–15. In any event, Plaintiffs need to be able to prepare Dr. Gozzo for her deposition by Sandoz, if the Court permits one.

Plaintiffs’ request for a Protective Order should be granted and Sandoz’s invocation of D.Del. LR 30.6 should be rejected.

The Honorable Jennifer L. Hall
September 15, 2020
Page 4

Respectfully,

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)

JBB/bac
Attachments

cc: All Counsel of Record (via electronic mail; w/attachments)

RULE 7.1.1 CERTIFICATE

I hereby certify that the subject of (1) Plaintiffs' request for protective order with respect to the Gozzo and Myerson depositions has been discussed with counsel for Sandoz and that we have not been able to reach agreement but (2) Sandoz's request for relief under D.Del. LR 30.6 has not been discussed between counsel.

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)

EXHIBIT A

From: [Kelson, Taylor J](#)
To: [Lydigsen, Laura](#); [Lee, Jieun](#); [Remus, Mark](#); [Sandoz Trintellix Team](#); [dgattuso@hegh.law](#); [RMarshall@hegh.law](#); [Schigelone, Jason](#)
Cc: [Trintellix](#); [jblumenfeld@mnat.com](#); [mdellinger@mnat.com](#)
Subject: H. Lundbeck A/S v. Apotex Inc., No. 1:18-cv-00088-LPS (D. Del.) (consolidated): '096 Patent Claims
Date: Wednesday, July 22, 2020 3:17:20 PM
Attachments: [image001.jpg](#)

Counsel,

We write regarding claims 4 and 5 of U.S. Patent No. 9,278,096, which are currently asserted against Sandoz. In light of the Court's Order (D.I. 814) granting Sandoz's Motion to Dismiss (D.I. 415) with respect to U.S. Patent Nos. 8,722,684, 8,969,355, 9,227,946, and 9,861,630, Plaintiffs will no longer assert claims 4 and 5 of U.S. Patent No. 9,278,096 against Sandoz in the present litigation. This does not in any way prejudice Plaintiffs' ability to assert claims which share elements or limitations with claims 4 and 5 of U.S. Patent No. 9,278,096 against Sandoz in the future, including claims of U.S. Patent Nos. 8,722,684, 8,969,355, 9,227,946, and 9,861,630.

Given that Plaintiffs are no longer asserting claims 4 and 5 of the '096 Patent against Sandoz in the present action, we understand that Sandoz will no longer seek to depose Drs. Myerson and Gozzo. Please confirm that our understanding is correct.

Regards,
Taylor

Taylor Kelson

Covington & Burling LLP
The New York Times Building, 620 Eighth Avenue
New York, NY 10018-1405
T +1 212 841 1275 | tkelson@cov.com
www.cov.com



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**EXHIBITS B-G
REDACTED IN THEIR ENTIRETY**

EXHIBIT H

From: [Sullivan, Thomas](#)
To: [Lydigsen, Laura](#)
Cc: [Trintellix](#); [Dellinger, Megan E.](#); [Blumenfeld, Jack \(JBlumenfeld@MNAT.com\)](#); [Remus, Mark](#); [Schigelone, Jason](#); [Lee, Jieun](#); [dgattuso@hegh.law](#); [RMarshall@hegh.law](#); [Sandoz Trintellix Team](#)
Subject: RE: H. Lundbeck A/S v. Apotex Inc., No. 1:18-cv-00088-LPS (D. Del.) (consolidated): Discovery Dispute Teleconference
Date: Friday, September 11, 2020 4:21:01 PM
Attachments: [image004.jpg](#)
[image001.jpg](#)

Laura,

Sandoz's request does not make sense. Delaware Local Rule 30.6 does not apply here because Sandoz's deposition of Dr. Gozzo never began. If Sandoz is going to ask the Court to prevent Plaintiffs' counsel from speaking with the witness in preparation for any eventual deposition, Sandoz should make its case in an opening letter so that Plaintiffs may understand the basis for that request, along with any supporting authority, and respond. At present, Sandoz has provided us with no basis to believe that Delaware Local Rule 30.6 applies in this situation. Demanding that Plaintiffs preemptively respond to an issue inserted into the dispute letter at the eleventh hour by Sandoz, which the parties did not discuss during any meet and confer and which Sandoz has not explained, is prejudicial to Plaintiffs and improper under Judge Hall's procedure. If Sandoz raises the issue first the first time in its responsive letter, we will ask the Court to disregard the request.

Regards,

Tom

Thomas Sullivan

Covington & Burling LLP
One CityCenter, 850 Tenth Street, NW
Washington, DC 20001-4956
T +1 202 662 5245 | tsullivan@cov.com
www.cov.com

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From: Lydigsen, Laura <llydigsen@brinksgilson.com>
Sent: Friday, September 11, 2020 1:43 PM
To: Sullivan, Thomas <TSullivan@cov.com>
Cc: Trintellix <Trintellix@cov.com>; Dellinger, Megan E. <mdellinger@MNAT.com>; Blumenfeld, Jack (JBlumenfeld@MNAT.com) <JBlumenfeld@MNAT.com>; Remus, Mark <mremus@brinksgilson.com>; Schigelone, Jason <JSchigelone@brinksgilson.com>; Lee, Jieun <jlee@brinksgilson.com>; dgattuso@hegh.law; RMarshall@hegh.law; Sandoz Trintellix Team <SandozTrintellixTeam@brinksgilson.com>
Subject: RE: H. Lundbeck A/S v. Apotex Inc., No. 1:18-cv-00088-LPS (D. Del.) (consolidated):

Discovery Dispute Teleconference

[EXTERNAL]

Dear Tom-

Sandoz is not withdrawing its request or otherwise waiving the protections of Del. L. R. 30.6, which automatically applies to all depositions in this action and bars Plaintiffs from consulting or conferring with Dr. Gozzo until Sandoz's portion of her deposition concludes.

The issue of whether Del. L. R. 30.6 applies is contingent on the first disputed issue raised in the parties' September 2 joint letter, which was raised by Plaintiffs. If the court grants Plaintiffs' request, then the issue of whether Del. L. R. 30.6 applies is moot. Under the circumstances, it makes no sense for Sandoz to submit an opening brief on this issue. In the interim, we expect Plaintiffs to comply with Del. L. R. 30.6 until Plaintiffs' request for relief is decided by the court.

Regards,

Laura

Laura Lydigsen

Intellectual Property Attorney

312.321.4894 | Direct

312.485.3872 | Mobile

llydigsen@brinksgilson.com

[Lydigsen Biography](#)

www.brinksgilson.com



Assistant: Connie Beam

312.245.3453 | cbeam@brinksgilson.com

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NBC Tower - Suite 3600 | 455 N. Cityfront Plaza Drive | Chicago, IL 60611

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From: Sullivan, Thomas <TSullivan@cov.com>

Sent: Thursday, September 10, 2020 1:42 PM

To: Lydigsen, Laura <llydigsen@brinksgilson.com>

Cc: Trintellix <Trintellix@cov.com>; Dellinger, Megan E. <mdellinger@MNAT.com>; Blumenfeld, Jack (<JBlumenfeld@MNAT.com> <JBlumenfeld@MNAT.com>); Remus, Mark (<mremus@brinksgilson.com>); Schigelone, Jason (<JSchigelone@brinksgilson.com>); Lee, Jieun

<jlee@brinksgilson.com>; dgattuso@hegh.law; RMarshall@hegh.law; Sandoz Trintellix Team
<SandozTrintellixTeam@brinksgilson.com>

Subject: [EXT] RE: H. Lundbeck A/S v. Apotex Inc., No. 1:18-cv-00088-LPS (D. Del.) (consolidated):
Discovery Dispute Teleconference

Laura,

In light of your intention to forgo filing an opening brief, Plaintiffs understand that Sandoz is withdrawing its request that Plaintiffs be prevented from communicating with Dr. Gozzo until such time that Sandoz is allowed to proceed with its independent deposition. Recall that Sandoz, not Plaintiffs, specifically raised this issue and requested the corresponding relief. See September 1, 2020, email from J. Schigelone to T. Sullivan (received at 4:20 PM EDT) (demanding that Dr. Gozzo's deposition be held open); September 2, 2020, email from J. Schigelone to T. Sullivan (received at 2:10 PM EDT) (Sandoz's edits to joint letter inserting request that Plaintiffs' communication with Dr. Gozzo be limited).

Best,
Tom

Thomas Sullivan

Covington & Burling LLP
One CityCenter, 850 Tenth Street, NW
Washington, DC 20001-4956
T +1 202 662 5245 | tsullivan@cov.com
www.cov.com

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From: Lydigsen, Laura <llydigsen@brinksgilson.com>
Sent: Thursday, September 10, 2020 12:18 PM
To: Sullivan, Thomas <TSullivan@cov.com>
Cc: Trintellix <Trintellix@cov.com>; Dellinger, Megan E. <mdellinger@MNAT.com>; Blumenfeld, Jack (<JBlumenfeld@MNAT.com> <JBlumenfeld@MNAT.com>); Remus, Mark (<mremus@brinksgilson.com> <mremus@brinksgilson.com>); Schigelone, Jason <JSchigelone@brinksgilson.com>; Lee, Jieun <jlee@brinksgilson.com>; dgattuso@hegh.law; RMarshall@hegh.law; Sandoz Trintellix Team <SandozTrintellixTeam@brinksgilson.com>
Subject: RE: H. Lundbeck A/S v. Apotex Inc., No. 1:18-cv-00088-LPS (D. Del.) (consolidated):
Discovery Dispute Teleconference

[EXTERNAL]

Dear Tom -

Sandoz does not intend to file an opening brief on any of the issues in the joint dispute letter. This is Plaintiffs' dispute that was created when Plaintiffs unilaterally excluded Sandoz from the Gozzo deposition in order to seek a protective order. The three bullet points are simply intertwined issues within that single dispute. Sandoz will only be filing an opposition letter.

Regards,

Laura

Laura Lydigsen

Intellectual Property Attorney

312.321.4894 | Direct

312.485.3872 | Mobile

llydigsen@brinksgilson.com

[Lydigsen Biography](#)

www.brinksgilson.com



Assistant: Connie Beam

312.245.3453 | cbeam@brinksgilson.com

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NBC Tower - Suite 3600 | 455 N. Cityfront Plaza Drive | Chicago, IL 60611

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From: Remus, Mark <mremus@brinksgilson.com>

Sent: Wednesday, September 9, 2020 2:13 PM

To: Sullivan, Thomas <TSullivan@cov.com>; Schigelone, Jason <JSchigelone@brinksgilson.com>;

Lydigsen, Laura <llydigsen@brinksgilson.com>; Lee, Jieun <jlee@brinksgilson.com>;

dgattuso@hegh.law; RMarshall@hegh.law

Cc: Trintellix <Trintellix@cov.com>; Dellinger, Megan E. <mdellinger@MNAT.com>; Blumenfeld, Jack (JBlumenfeld@MNAT.com) <JBlumenfeld@MNAT.com>

Subject: RE: H. Lundbeck A/S v. Apotex Inc., No. 1:18-cv-00088-LPS (D. Del.) (consolidated):
Discovery Dispute Teleconference

Tom-

Our team is tied up with depositions today and will not be able to respond within your requested 2 hour deadline. We will consider your request and get back to you as soon as possible.

-Mark

Mark Remus

Intellectual Property Attorney

312.321.4720 | Direct

312.404.0328 | Mobile

mremus@brinksgilson.com

www.brinksgilson.com



BRINKS GILSON & LIONE

NBC Tower - Suite 3600 | 455 N. Cityfront Plaza Drive | Chicago, IL 60611

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From: Sullivan, Thomas <TSullivan@cov.com>

Sent: Wednesday, September 9, 2020 2:01 PM

To: Schigelone, Jason <JSchigelone@brinksgilson.com>; Remus, Mark <mremus@brinksgilson.com>; Lydigsen, Laura <llydigsen@brinksgilson.com>; Lee, Jieun <jlee@brinksgilson.com>; dgattuso@hegh.law; RMarshall@hegh.law

Cc: Trintellix <Trintellix@cov.com>; Dellinger, Megan E. <mdellinger@MNAT.com>; Blumenfeld, Jack (JBlumenfeld@MNAT.com) <JBlumenfeld@MNAT.com>

Subject: [EXT] H. Lundbeck A/S v. Apotex Inc., No. 1:18-cv-00088-LPS (D. Del.) (consolidated):
Discovery Dispute Teleconference

Caution - External Email

Counsel,

The Court's September 8, 2020, Oral Order regarding the parties' discovery disputes requires "the party(ies) seeking relief shall file with the Court a letter, not to exceed three pages, in no less than 12-point font, outlining the issues in dispute and its position on those issues," by no later than September 15, 2020. D.I. 941. To avoid any confusion as to which issue should be addressed in the respective opening letter briefs, please confirm by COB today that Sandoz is requesting relief regarding the second and third issues identified in the parties' joint dispute letter, and Plaintiffs' request for relief is limited to the first issue.

Regards,

Tom

Thomas Sullivan

Covington & Burling LLP

One CityCenter, 850 Tenth Street, NW

Washington, DC 20001-4956

T +1 202 662 5245 | tsullivan@cov.com

www.cov.com

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